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Oysterville, Wa. 98641
April 14, 1999

William K. Hubbard
Dockets Mgmt. Branch (HFA-3057)
Food & Drug Administration
563 Fishers Lane, Room 1061
Rockville, Md. 20852

99 APR 22 AM 10:26

Re: Federal Register request for Standard for Vibrio--
Vulnificus Docket #98P-0504 Volume 64 No. 13
Page 3300-3301

Dear Mr. Hubbard,

The petition brought by CSPI to require post-harvest for all shellfish from areas with detectable levels of Vibrio vulnificus fails to stand the test of common sense in protecting public health.

My family has been in the oyster business for 70 years in Willapa Bay. During this time I am only aware of one episode of Vibrio illness. The company responsible is very small and deals solely with live oysters in the shell. Their practice has been to hold oysters in a shallow tidal pool, 2 or 3 inches deep near shore. At this location on a good low tide the tide will go out a half mile. On a summer day these oysters are exposed for hours to the hot sun. When the tide does come in the water is warmed up to well over 70° coming across the warm sand. This is a matter that can well be handled by the Health Dept. as it is illegal.

Growers like myself in Willapa Bay sell our oysters to opening houses for $15.00 to $16.00 per gallon. This year most oysters are going from about 150 to over 200 per gallon. This figures out we are getting about 7½¢ to 10¢ per oyster. You don't have to be a rocket scientist to understand what adding a cost of 8¢ per oyster will do to our ability to make a profit.

Because I see no real reason for this CSPI petition on the west coast I am wondering if there is a connection between CSPI and the AmeriPure Company. Perhaps the beef industry is involved. In the past the've been known to pull a few strings to "beef up" their share of the market. Whatever the reason, it isn't public health.

Sincerely,
HECKES OYSTER CO.

Peter G. Heckes

Peter G. Heckes

PGH:r

98P-0504

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No more live oysters on the half shell?

■ Federal rule aimed at Gulf and Atlantic coasts could doom many NW growers

By ED HUNT
Observer science writer

BAY CENTER—The U.S. Food and Drug Administration is considering action that could take raw oysters off the menu and push as many as 75 percent of shellfish growers out of business across the nation, according to the Pacific Coast Oyster Growers Association.

The Center for Science in the Public Interest—a national advocacy group based in Washington, D.C—is asking the FDA for stricter controls on the sale of raw oysters and other shellfish.

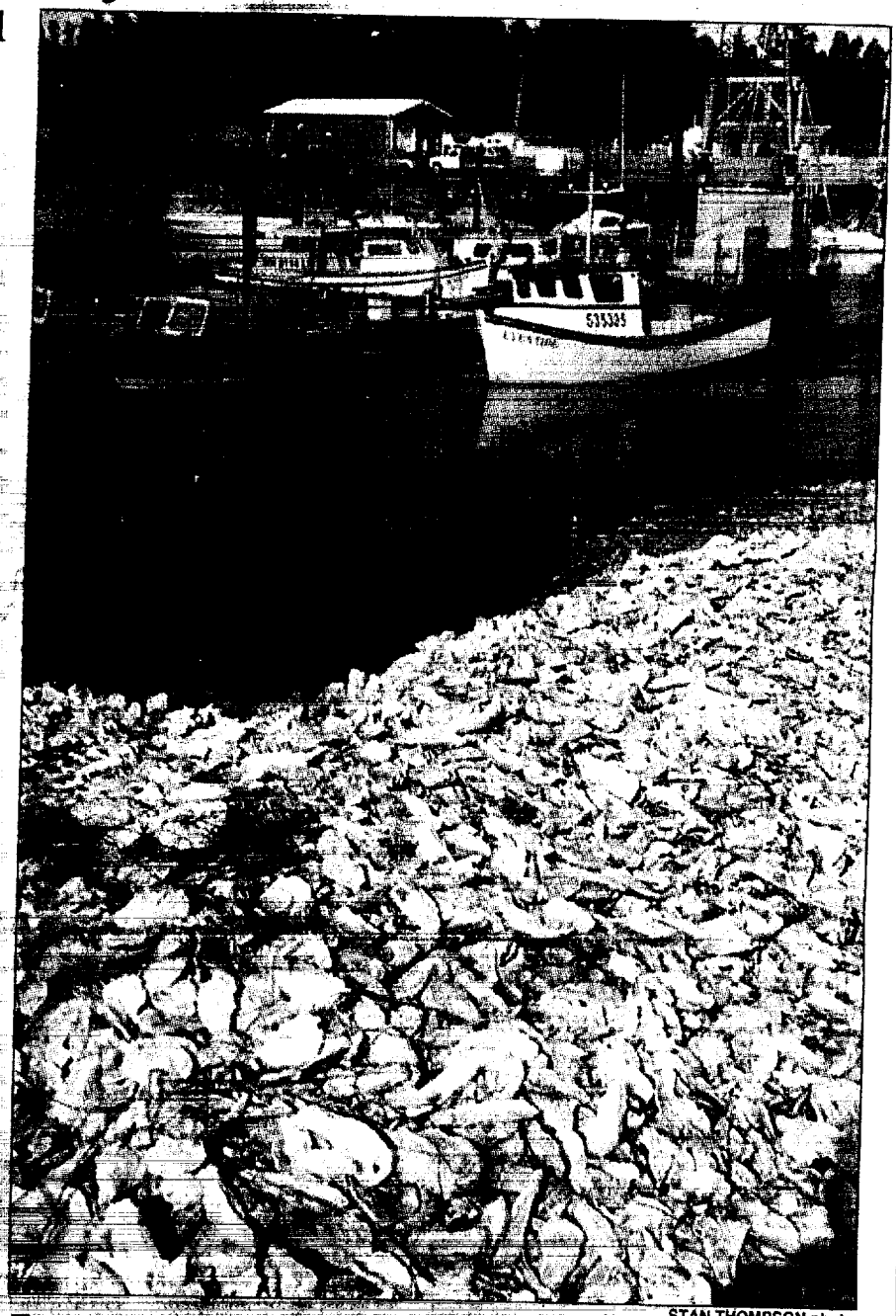
'This is quite serious. It could wipe a lot of people out.'

Dick Wilson
Owner of Bay Center Mariculture

While the action is directed against Gulf and Atlantic coast growers, it may have dire consequences for Pacific Coast growers who already operate under shellfish safety measures at the state level but who face less danger from shellfish safety problems than growers in warmer waters.

"We really don't see it as a West Coast problem," said Darren Mitchell, staff attorney for CSPI. "It's really a Gulf Coast problem. The performance standard we are calling for is for all waters in which deaths or illness have been attributed to *Vibrio vulnificus*."

The group filed a petition in June 1998 asking the FDA to force Gulf Coast growers to "eliminate certain dangerous bacteria from its oysters." According to the group, the petition asks FDA to require that shellfish sold for raw consumption be free of the bacteria, called *Vibrio vulnificus*. Virtually all of the 177 reported cases



STAN THOMPSON photo

The oyster business is a key part of the economy in Nahcotta, South Bend, Bay Center and Oysterville, but a proposed federal rule places those jobs at risk. Growers rely on lucrative sales of oysters for consumption live on the half shell. The new rule would require oysters to go through an expensive process before sale that kills bacteria and the oyster itself. Though the oysters can still be eaten in the shell, they must be eaten within hours, or else they become rubbery.

See Oysters on Page A7

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since 1989 have been linked to the warm waters of the Gulf of Mexico or Florida's Atlantic Coast.

The potential impact to West Coast growers stems from the different standards and different water conditions faced by shellfish growers on the Pacific and Atlantic coasts and the Gulf of Mexico, explained Kathleen Sayce, bank scientist with Shorebank Pacific in Ilwaco. Sayce said the type of bacteria the advocacy group is targeting is naturally occuring in all coastal waters of the United States. It doesn't become harmful until water temperature exceeds 20 or 21 degrees Celsius, or about 68 degrees F.

Pacific coast waters—especially those in Willapa Bay—rarely get that warm, although they did reach these temperatures during the recent extreme El Niño event, which suppressed the upwelling of cool waters off the Northwest coast and attracted tropical fish to Washington's marine waters. On the East Coast, and particularly the Gulf Coast of the U.S., the water often exceeds these temperatures thanks to the warm water of the Gulf Stream.

Sayce says that state regulations for West Coast and East Coast growers also differ significantly. Pacific Coast growers have limits on the amount of bacteria that can be present in the water before an area is closed to harvest; on the East Coast, growers have resisted such standards, and handling practices there often allow growers to circumvent protections, Sayce said.

"The rules for shellfish handling in the West are much more stringent than they are in the East, and 30 to 40 people get sick and die back there every year." Sayce said. "That's no overstatement—eating shellfish in those states is much riskier. I don't know how they've gotten away with it. It's amazing that those states haven't stepped in asked that the matter be referred to the Interstate Shellfish Sanitation Conference, which is made up of state and federal health regulators and member of the industry. The ISSC debates public health issues in detail and tries to bring in the best available science. It also tries to makes sure that whatever regulatory changes are being proposed can actually be implemented by the growers, Downey said.

"There will never be enough enforcement officers out to enforce these laws, so we need to self regulate," Downey said. "So we've asked that FDA to refer it to the ISSC and to give funding to do the science we need to come up with the best regulation possible—not just non-detectable. If the level is set at non-detectable, that's going to mean no more raw oysters."

Pacific oyster growers are asking that the tighter controls they put in after 1997 continue to be used for two more years while research is stepped up and self regulation is tightened. Consumer education and pulling the product during warm weather events is important as well, Downey said.

However, it's also important not to change procedures—possibly impacting the whole West Coast industry—based on what could be anomalous weather events, Downey added.

Mitchell said his health advocacy group is still not happy with the controls in place because they "require someone to get sick before shutting down shellfish harvesting" because the current threshold is set too high.

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Kathleen Sayce
Peninsula biologist

method called AmeriPure. Irradiation is before the FDA and is likely to be approved and pressurization techniques are under development, Mitchell said.

The problem, says Downey, is that the growers she represents are mostly small "mom and pop" type operations that would never be able to afford to pay $250,000 for the pasteurization machine. Additionally, the market wouldn't support simply passing the cost on to consumers as Mitchell's organization suggests.

NW industry at risk of destruction

Downey says the pasteurization process kills the oyster and a rubber band is needed to keep the oyster shell shut. If eaten a few hours after cooking it tastes like a raw oyster, she says, "but if you wait too long, it tastes like rubber bands.

"A majority of shellfish growers would be brought to their knees and the market would not be able to bear it," Downey said. "Since AmeriPure has the only approved process, it's a sweet deal for them, but it will wipe out 75 percent of growers across the country. Small mom and pop growers can't do this sort of retrofit. This has huge economic implications." Downey said requiring that no dectectable bacteria be present in oysters could force 75 percent of the nation's growers out of business and would eliminate the sale of raw oysters.

For Pacific Coast growers, selling raw or live oysters has become a mainstay of their business. Great tasting oysters live and in the shell can fetch a higher price in a business with narrow margins.

gotten away with it. It's amazing that those states haven't stepped in and said 'We've got to do something."

The strain of bacteria is different as well, Sayce said. While *Vibrio vulnificus* is present in West Coast waters, a different, less harmful type of the bacteria—*Vibrio parahaemolyticus*—is much more common. (See related story.)

Because a number of illnesses were reported in 1997 due to *Vibrio parahaemolyticus,* the petition also calls for FDA to take a closer look at the standards of acceptable concentrations of this bacteria as well, said Robin Downey, executive director for the Pacific Coast Oyster Growers Association.

After the warm waters of an emerging El Niño caused a West Coast outbreak in 1997, Pacific Coast Oyster Growers lowered the threshold for Vibrio concentrations and imposed a voluntary shutdown of raw oyster sales when waters became unusually warm again in 1998. Downey said this avoided many illnesses and is proof that the self regulation of West Coast growers works.

Two bacteria lumped together

Downey is worried that the two different strains of Vibrio are being lumped together. No deaths or long-term effects have been found from *Vibrio parahaemolyticus* (VP). She's afraid FDA will adopt a requirement for no detectable bacteria. Such a requirement would put an end to raw shellfish sales because there is usually a non-harmful amount of bacteria naturally occurring in the water.

"We're between a rock and hard place in terms of public health," Downey said. "We should consider setting a new standard, but the standard should not be set at zero. The petition says we might as well set a new standard for VP while we're at it, but they don't suggest what kind of standard should be set."

The Pacific Coast growers have [illegible] because the current threshold is set too high.

However, he agrees with PCOGA that more research needs to be done to set a "safe" level of Vibrio and a threshold to trigger a harvest shutdown. Yet, Mitchell says his group does not want to see this process go through the ISSC.

"It's really time for the FDA to step in," Mitchell said. "They really have the authority to come up with performance standards that everyone should meet."

Mitchell said FDA needs to require that growers determine what hazards are applicable to their product and develop and put in place controls for those hazards in their processing.

One way to control those hazards would be simply to delay harvest—or to harvest, but sell only for the cooked market—which is how Pacific Coast growers handled things in 1998, Mitchell admitted.

"There's no doubt that Pacific Coast growers acted responsibly," Mitchell said. "But the response is too late when you wait for human illness to trigger it. It needs to be more pro-active. They need to take that no-harvest step when Vibrio are above a truly accurate threshold.The key is where to set that number."

"We agree that more science needs to be done." Mitchell continued. "It's way too high where it is now, and even PCOGA agrees with that." Mitchell says that if FDA puts in place a requirement to reduce pathogens in shellfish, the technology providers will come up with new technology to meet the need for a way to kill the bacteria.

Already there is one method approved by FDA and on the market—a patented heat pasteurization [illegible] in the shell can fetch a higher price in a business with narrow margins. If the FDA forces them to use a process that kills all bacteria they could lose that market altogether.

"This has become a big part of our business," said Dick Wilson, owner of Bay Center Mariculture. "Last year we shipped 120,000 dozen, this year we'll probably do more. But they want the oyster live and cold in the shell. You can get a cooked oyster anywhere."

In fact, it could impact any shellfish that comes out of U.S. coastal water, Wilson said.

"This is quite serious," Wilson said. "It could wipe a lot of people out. It would really hurt the business and market we've built." Downey argues that there are much greater health risks for the FDA to concern itself with. More people get sick from mayonnaise than from Pacific Coast oysters.

"This thing has been around as long as human history and it's ridiculous to suddenly force people to go with a completely different product," Downey said. "So we're hoping the FDA will look at the true health impact, the anomalous weather and the dearth of science and allow us to put a control plan into effect. If there is enough of a political response urging them to do that, they'll do that right thing. We have reason on our side."

The FDA is currently taking comments on what action it should take. Comments can be sent to William Hubbard, Document Management Branch, HFA-305, FDA, 5630, Fisher's Lane, Rm. 1061, Rockville MD, 20852. Refer to Document No. 98p-0504 by April 21.

Ed Hunt is the editor of the Tidepool.org internet news service.

Sorting out shellfish safety

VIBRIO VULNIFICUS: A naturally occurring class of bacteria that becomes active when the water gets warm. The bacteria is rendered harmless by cooking. Eaten in raw shellfish, it can cause illness, particularly in people with compromised immune systems (AIDS, liver disease or undergoing certain cancer treatments), as well as children and the elderly. In some cases it can cause death.

Vibrio outbreaks are very common on the Eastern and Gulf coasts where the Gulf Stream warms the waters. A number of illnesses are reported every year. Virtually all of the 177 reported cases since 1989 have been linked to the warm waters of the Gulf of Mexico or Florida's Atlantic Coast.

Vibrio parahaemolyticus is more common on the West Coast. It seems to have less severe illnesses associated with it and causes flu-like symptoms with no reports of death or long term effects. Because Pacific Coast waters rarely get above 20 degrees Celsius, outbreaks are rare. Warm weather in 1997 and 1998 increased West Coast water temperatures to unusually high levels and forced limits on the sale of raw shellfish.

PSP: The acronym stands for Paralytic Shellfish Poisoning, contracted by eating shellfish with this naturally-occurring toxin. It's actually saxitoxin, which is produced by 50 to 100 species of tiny critters called dinoflagelates. The dinoflagelates like the warm sunny weather, and outbreaks can be found on razor clams during the late summer and early fall. It is sometimes referred to as "Red Tide."

DOMOIC ACID: Refers to a biotoxin produced by a group of diatoms called *Pseudo-nitzschia.* While scientists can predict the conditions that lead to an outbreak of Vibrio or PSP, domoic acid is much harder to predict, according to local scientist Kathleen Sayce.

The *Pseudo-nitzschia* don't always produce the toxin and scientists are still trying to figure out what conditions trigger its release. That's caused frustration for Department of Health officials trying to manage safe recreational clam harvests because a beach on one side of the Peninsula may have high concentrations of the toxin, while just over in Willapa Bay there's no trace.

Sayce says a recent study found that a lack of nutrients such as phosphorus and silica may trigger domoic acid production. Therefore, large amounts of nutrients washing down rivers into Willapa Bay may keep domoic acid production down inside the bay.

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